COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17-VIII-2004
C(2004)3246

NOT FOR PUBLICATION

**COMMISSION DECISION**

**of 17-VIII-2004**

**on the renewal of the marketing authorisation for "Cetrotide - Cetrorelix (as acetate)" the medicinal product for human use granted by Decision C(1999)939**

ONLY THE ENGLISH TEXT IS AUTHENTIC

**COMMISSION DECISION**

**of 17-VIII-2004**

**on the renewal of the marketing authorisation for "Cetrotide - Cetrorelix (as acetate)" the medicinal product for human use granted by Decision C(1999)939**

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2], and in particular Article 10(2) thereof,

Having regard to the application submitted by Serono Europe Ltd., on 13 January 2004, under Article 13(1) of Regulation (EEC) No 2309/93 with a view to the renewal of the marketing authorisation for the medicinal product "Cetrotide - Cetrorelix (as acetate)"

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products on 24 March 2004,

Whereas:

(1) After consideration by the Agency of a dossier containing up-to-date information on pharmacovigilance, it appears that the medicinal product "Cetrotide - Cetrorelix (as acetate)" entered in the Community register of medicinal products under Nos EU/1/99/100/001-003 and authorised by Commission Decision C(1999)939 of 13 April 1999, complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3] as amended by Directive 2002/98/EC[4] and by Directive 2003/63/EC[5].

(2) The marketing authorisation which expires on 15 April 2004 should therefore be renewed.

[1] OJ L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 311, 28.11.2001, p. 67.
[4] OJ L 33, 8.2.2003, p. 30.
[5] OJ L 159, 27.6.2003, p. 46.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

*Article 1*

The marketing authorisation granted by Decision C(1999)939 of 13 April 1999 which expires on 15 April 2004 is renewed.

*Article 2*

Decision C(1999)939 is amended as follows:

a) Annex I is replaced by Annex I to this Decision;

b) Annex II is replaced by Annex II to this Decision;

c) Annex III (A and B) is replaced by Annex III to this Decision.

*Article 3*

The period of validity of the renewed authorization shall be five years from 15 April 2004.

*Article 4*

This Decision is addressed to Serono Europe Ltd., 56, Marsh Wall, London E14 9TP, United Kingdom.

Done at Brussels, 17-VIII-2004

*For the Commission*
*Olli REHN*
*Member of the Commission*